K081542

JUN 27 2008

SECTION 12. 510(K) SUMMARY

12.1 ADMINISTRATIVE INFORMATION

12.1.1 Name and address

Sponsor:
Entellus Medical, Inc.
6705 Wedgwood Court N,
Maple Grove, MN 55311
Tel: 1-763-463-1595
Fax: 1-763-463-1599

FDA Est. Reg #: NA
Owner/Operator# 10025424

Submitted on behalf of sponsor by:
Sew-Wah Tay, Ph.D. (Regulatory Consultant)
18555 37th Ave North
Plymouth, MN 55446
Tel: 612-801-6782
Fax: 763-208-4465
Email: swtay@libramed.com

Date Prepared: May 30, 2008

12.1.2 Device Name

Trade Name	Entellus Medical FinESS Sinus Treatment
Common Name	Trans-mucocutaneous Sinus Access and Dilation Catheter System
Classification Name	Ear, nose, and throat electric or pneumatic surgical drill
Classification	21 CFR 874.4420 Class II
Product Code	LRC

12.2 INDICATION FOR USE

To access and treat the sinus and its outflow tract with a trans-antral approach in adults. The bony sinus outflow tract is remodeled by balloon displacement of adjacent bone and paranasal sinuses.

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12.3 DEVICE DESCRIPTION

The Entellus Medical FinESS Sinus Treatment allows for trans-antral access of the maxillary sinus, placement of the balloon catheter with endoscopic guidance at the ostium and infundibulum. The ostium and infundibulum is widened by balloon dilated using saline.

12.4 SUBSTANTIAL EQUIVALENCE

The Entellus Medical FinESS Sinus Treatment is substantially equivalent to the previously cleared device (K072302).

The Entellus Medical FinESS Sinus Treatment (FinESS) has the same Intended Use as its predicate. Like its predicate, it uses balloon to dilate tissue to remodel the sinus structures.

12.5 PERFORMANCE DATA

The device performance test data is provided in the 510(k) submission. The performance data demonstrates that the device meets specification, is biocompatible and meets sterility standards. Performance testing included biocompatibility testing, dimensional verification, bench testing, and simulated use testing and showed that the device meets design specification and performed as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 2008

Entellus Medical
c/o Sew-Wah Tay, PhD
Regulatory Consultant
Libra Medical, LLC
18555 37th Ave. N.
Plymouth, MN 55446

Re: K081542
Trade/Device Name: Entellus FinESS Sinus Treatment
Regulation Number: 21 CFR 874.4420
Regulation Name: Ear, nose, and throat manual surgical instrument
Regulatory Class: Class I
Product Code: LRC
Dated: June 23, 2008
Received: June 24, 2008

Dear Dr. Tay:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K081542

SECTION 7. INDICATION FOR USE STATEMENT

510(k) Number (if known): K081542

Device Name: Entellus Medical FinESS Sinus Treatment

Indications for Use

To access and treat the sinus and its outflow tract with a trans-antral approach in adults. The bony sinus outflow tract is remodeled by balloon displacement of adjacent bone and paranasal sinuses

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

6/26/08

(Division Sign-Off)
Division of
Nose and

510(k) Number K081542

Prescription Use ___X___ - OR/AND Over-the-Counter Use_____